IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. 18-1025-CFC |
| CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH, | ) | |
| Defendants. | ) | |

**DEFENDANTS' ANSWERING BRIEF IN**
**OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS**

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## INTRODUCTION

Defendants Celltrion, Celltrion Healthcare, Teva Pharmaceuticals USA, and Teva Pharmaceuticals International GmbH (collectively, "Celltrion") are currently seeking approval under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") to market a biological drug called trastuzumab. In a related suit filed earlier this year and also pending in this Court,[1] plaintiffs Genentech, Hoffmann-La Roche, and City of Hope (collectively, "Genentech") allege that Celltrion's commercial launch of its proposed trastuzumab product will infringe dozens of Genentech's patents. Consistent with "standard practice" in patent infringement cases, Celltrion filed counterclaims in that action seeking declarations of noninfringement or invalidity with respect to 38 of the patents-in-suit. 6 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1406 (3d ed. 2018) (noting the widespread consensus "that when plaintiff's claim is for patent infringement, defendant may counterclaim for a declaration of the invalidity or noninfringement of the patent"). Genentech moved to dismiss those counterclaims, arguing that they were barred by the BPCIA because Celltrion supposedly had failed to complete certain steps of the BPCIA's "patent dance."

Hedging its bets, Genentech also filed this suit—a suit that is expressly premised on the fact that Celltrion *did* complete all required steps of the patent dance. Specifically, Genentech brought this action under 42 U.S.C. § 262(*l*)(6), which is only triggered if the parties have finished the preceding steps of the patent dance. Compl., D.I. 1, ¶ 17. Thus, the only reason for *this* suit to move forward is if the Court agrees that Celltrion has complied with its obligations under 42 U.S.C. § 262(*l*). But despite this suit's premise, Genentech has once again moved to dismiss Celltrion's counterclaims, reprising its argument that the counterclaims are barred by the

[1] *Genentech, Inc., et al. v. Celltrion, Inc., et al.*, C.A. No. 18-95-CFC

BPCIA because Celltrion supposedly did not complete certain steps of the patent dance. This Court should deny the motion for either of two independently sufficient reasons.

First, as Celltrion explained in its opposition to Genentech's motion to dismiss in the first case, Genentech's motion relies on a statutory provision, section 262(*l*)(9)(B), that only imposes restrictions on a biosimilar applicant's ability to "bring an action"—not on its ability to file counterclaims in an existing action. Indeed, the Third Circuit has made clear in a decision interpreting indistinguishable statutory language that a "defendant does not 'bring an action' by asserting a counterclaim." *Jonathan H. v. Souderton Area Sch. Dist.*, 562 F.3d 527, 529-30 (3d Cir. 2009). Genentech only references this decision in passing (Pls.' Br., D.I. 16, at 16), and provides no basis to distinguish it.

Second, as noted, the current suit proceeds from the premise that Celltrion *has* completed the steps of the patent dance that Genentech identifies. And that premise is true. Accordingly, the central contention of Genentech's motion—that Celltrion has failed to complete certain steps of the patent dance—is simply incorrect. In short, Genentech has identified no statutory basis to bar Celltrion's counterclaims in this action.

## NATURE AND STAGE OF THE PROCEEDINGS

Genentech filed this action for patent infringement on July 11, 2018. Celltrion timely answered the complaint and filed counterclaims on August 17, 2018. Genentech brought the pending motion to dismiss on September 7, 2018.

## STATEMENT OF FACTS

Celltrion is currently seeking FDA approval to develop and market a biological medication. Compl., D.I. 1, ¶ 7. The product—which Celltrion seeks approval to market under the brand name Herzuma—is a proposed "biosimilar" to Genentech's drug Herceptin, which FDA approved 20 years ago. *Id.* ¶¶ 5, 7, 50. Herceptin and Herzuma both contain trastuzumab,

an antibody used to treat certain forms of cancer. *Id.* ¶¶ 3, 50. In an effort to bring competition to the market for this life-saving product, Celltrion has devoted significant time and resources over the past several years to developing and testing Herzuma.

Because Herzuma is a proposed biosimilar of Herceptin, the BPCIA allows Celltrion to follow an abbreviated pathway to FDA licensure that relies in part on the fact that FDA has already approved Herceptin (which the BPCIA calls the "reference product"). *See* 42 U.S.C. §§ 262(i)(4), (k). In accordance with this statutory scheme, Celltrion submitted an "abbreviated biologic license application" ("aBLA") to FDA on May 30, 2017, and the agency notified Celltrion that it had accepted the application on July 28, 2017. Defs.' Countercls., D.I. 7, ¶ 15. Celltrion and Genentech then exchanged information in several stages according to the provisions of the BPCIA—a process known as the "patent dance."

Celltrion began that process on August 11, 2017, sending Genentech (the "reference product sponsor") a copy of its aBLA and information regarding the manufacturing process for Herzuma. *See* 42 U.S.C. §§ 262(*l*)(1)(A), (*l*)(2); Countercls. ¶ 17. Celltrion's disclosure comprised more than 280,000 pages of technical details and batch records describing Herzuma and its method of manufacture, including (i) the source, history, and generation of the cell substrate; (ii) the cell culture and harvest process; (iii) each and every purification process step; and (iv) raw materials used during the manufacture of Herzuma. Countercls. ¶ 17.

On October 10, 2017, Genentech provided Celltrion with its "(3)(A) List," a document identifying the patents for which it "believe[d] a claim of patent infringement could reasonably be asserted" against Celltrion for marketing Herzuma. 42 U.S.C. § 262(*l*)(3)(A)(i); *see* Compl. ¶ 40. The list comprised the same 40 patents that Genentech is now asserting in this action. Compl. ¶¶ 53-55; Countercls. ¶ 19. Celltrion timely responded on November 7, 2017, by

providing its "(3)(B) Statement." *See* 42 U.S.C. § 262(*l*)(3)(B)(ii); Countercls. ¶ 59. In it, Celltrion stated that it did not intend to market Herzuma before two of the listed patents expired (on June 12, 2018). *See* 42 U.S.C. § 262(*l*)(3)(B)(ii)(II); Countercls. ¶ 61. As to the other 38 patents, Celltrion provided a detailed explanation as to why the marketing of Herzuma would not result in infringement, or why the patents were otherwise invalid or unenforceable. *See* 42 U.S.C. § 262(*l*)(3)(B)(ii)(I); Compl. ¶ 41; Countercls. ¶ 61.

Genentech replied on January 5, 2018, with its "(3)(C) Statement"—a statement that describes "the factual and legal basis" for Genentech's opinion that its patents would be "infringed by the commercial marketing of the [biosimilar]." 42 U.S.C. § 262(*l*)(3)(C); Compl. ¶ 42. Notably, Genentech failed to provide any arguments as to the infringement or validity of 20 patents on the (3)(A) List. *See* Compl. ¶ 42; Countercls. ¶ 62. Nevertheless, Genentech refused to drop those 20 patents, and instead purported to reserve the right to assert infringement claims under those patents if it later decided that Celltrion's (3)(B) Statement had been incomplete or misleading. Countercls. ¶ 62. In a letter accompanying Genentech's (3)(C) statement and sent the same day, Genentech proposed that the 20 patents identified in that statement should "be included in the infringement action under § 262(*l*)(4)(A)." *Id.* ¶ 63.

On January 11, 2018, Celltrion wrote to Genentech indicating that, pursuant to section 262(*l*)(4)(A), it wished to litigate all of the patents on Genentech's (3)(A) List. Compl. ¶ 43; Countercls. ¶ 64. Celltrion further notified Genentech, pursuant to section 262(*l*)(8)(A), that commercial marketing of Herzuma would begin as early as 180 days from the date of the notice. Countercls. ¶ 65.

In light of the uncertainty created by Genentech's reservation of rights in its (3)(C) Statement, Celltrion also brought an action in the Northern District of California seeking a

declaration of noninfringement, invalidity, or unenforceability with respect to the 38 patents that Celltrion identified in its (3)(B) Statement. *See generally* First Am. Compl., D.I. 40, in *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274 (N.D. Cal., Feb. 8, 2018). Genentech responded by bringing an action in this District (the related suit, No. 18-95) and moving to dismiss the California suit.

As relevant here, Genentech's motion argued that paragraph (*l*)(9)(B) barred Celltrion's declaratory action because Celltrion supposedly had "fail[ed] to complete an action required of [it]" under paragraph (5). Defs.' Mot. to Dismiss, D.I. 53, at 11 in *Celltrion*, No. 4:18-cv-274 (N.D. Cal., Mar. 2, 2018) (quoting 42 U.S.C. § 262(*l*)(9)(B)). As Celltrion explained in opposing dismissal, however, Celltrion had satisfied the standards in 28 U.S.C. § 2201 for seeking declaratory relief, and nothing in the BPCIA barred its action. More specifically, Celltrion explained, it had carried out its obligations under paragraph (5) by providing notice to Genentech that it wished to litigate all of the patents on Genentech's paragraph (3)(A) List. *See generally* Pls.' Opp'n to Defs.' Mot. to Dismiss, D.I. 67, at 9-11, in *Celltrion*, No. 4:18-cv-274 (N.D. Cal., Mar. 21, 2018). Judge White ultimately disagreed, however, holding that paragraph (*l*)(9)(B) barred Celltrion's suit, on the theory that Celltrion had not completed its paragraph (5) obligations. *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274, 2018 WL 2448254, at *5 (N.D. Cal. May 9, 2018).

While Celltrion is appealing Judge White's ruling, Celltrion has nevertheless taken steps to complete the paragraph (5) exchanges to comply with Judge White's reading of the BPCIA. In particular, on June 6, 2018, Celltrion sent Genentech notice pursuant to section 262(*l*)(5)(A) that Celltrion would identify 40 patents in its paragraph (5)(B)(i)(I) list. Countercls. ¶ 67. And on June 11, 2018, the parties simultaneously exchanged lists pursuant to section 262(*l*)(5)(B)

identifying the patents that each party believes should be the subject of an action for patent infringement under paragraph (6). *Id.* ¶¶ 68-69. Thirty days after those exchanges, Genentech filed the current lawsuit as required by section 262(*l*)(6)(B), asserting the 40 patents identified in the lists exchanged by the parties. *See* Compl. ¶¶ 53-55. Celltrion answered the complaint on August 17, 2018, raising counterclaims for declaratory relief with respect to 38 of the patents in dispute. *See generally* D.I. 7. Genentech has now moved to dismiss those counterclaims.

## SUMMARY OF ARGUMENT

Under 42 U.S.C. § 262(*l*)(9)(B), a biosimilar applicant that "fails to complete an action required of [it] under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A)" of section 262(*l*) may not "bring an action" seeking "a declaration of infringement, validity, or enforceability." That statute does not bar Celltrion's counterclaims for two independent reasons.

First, section 262(*l*)(9)(B) only imposes restrictions on a biosimilar applicant's ability to "*bring* an action," not on its ability to file counterclaims in an *existing* action. That conclusion follows from the provision's plain language: to "bring an action" means "to institute legal proceedings." Black's Law Dictionary 219 (9th ed. 2009). Authorities interpreting both section 262(*l*)(9)(B) itself and materially indistinguishable statutory text confirm that "bringing an action" refers to the filing of a complaint at the start of a lawsuit—not filing a pleading at some later stage in already-pending litigation, such as an answer containing counterclaims. *See, e.g.*, *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015), *aff'd in part and vacated in part on other grounds*, 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part and vacated in part on other grounds*, 137 S. Ct. 1664 (2017); *Jonathan H. v. Souderton Area Sch. Dist.*, 562 F.3d 527, 529-30 (3d Cir. 2009); *Chandler v. D.C. Dep't of Corr.*, 145 F.3d 1355, 1359 (D.C. Cir. 1998); *Beeler-Lopez v. Dodeka, LLC*, 711 F. Supp. 2d 679, 681 (E.D. Tex.

2010); *see also, e.g.*, Fed. R. Civ. P. 3, 13. Genentech's contrary reading of the BPCIA is also inconsistent with the statute's purpose of providing certainty to biosimilar applicants, because it would allow the reference product sponsor to drop patents from litigation while continuing to wield a threat of future infringement liability after commercial launch.

Second, Celltrion did not "fail to complete" any of the actions specifically enumerated in section 262(*l*)(9)(B), and that provision therefore does not bar Celltrion from seeking relief in any form. Even assuming Judge White's interpretation of the BPCIA is correct, Celltrion has since completed all paragraph (5) exchanges with Genentech. Genentech insists that those exchanges were untimely, but its argument requires the Court to read into paragraph (5) a time limit that does not exist. Aside from its paragraph (5) arguments, Genentech also contends for the first time that Celltrion's action is barred because it supposedly did not provide notice of Genentech's suit as required under section 262(*l*)(6)(C)(i). But Celltrion in fact provided the relevant notice, which was not due until *after* Celltrion answered Genentech's (6)(C) complaint and filed its counterclaims. In short, Genentech's efforts to apply section 262(*l*)(9)(B) to Celltrion's counterclaims fail.

## ARGUMENT

### THE BPCIA DOES NOT BAR CELLTRION'S COUNTERCLAIMS.

Genentech's argument for dismissal rests on a single statutory provision: 42 U.S.C. § 262(*l*)(9)(B). Under that provision, a biosimilar applicant who "fails to complete an action required of [it] under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A)" of section 262(*l*) may not "bring an action" seeking "a declaration of infringement, validity, or enforceability." In its motion to dismiss, Genentech claims—largely in reliance on Judge White's non-binding opinion from the California litigation—that this language bars Celltrion's counterclaims.

As noted, Celltrion respectfully believes that Judge White's decision was incorrect. Judge White reasoned that section 262(*l*)(9)(B) barred Celltrion's declaratory action on the theory that Celltrion had not completed its paragraph (5) exchanges at the time it filed suit in California. *Celltrion*, 2018 WL 2448254, at *5. But as Celltrion explained in opposing Genentech's motion to dismiss in the California action, Celltrion *did* satisfy paragraph (5)'s requirements before filing suit: its notice to Genentech that it wished to litigate all of the patents on Genentech's (3)(A) List exhausted any discussions that might take place as part of a paragraph (5) exchange. *See* Pls.' Opp'n to Defs.' Mot. to Dismiss, D.I. 67, at 10-11, in *Celltrion*, No. 4:18-cv-274 (N.D. Cal., Mar. 21, 2018).

Even accepting Judge White's statutory interpretation, however, his decision is inapplicable here—and Genentech's reliance on section 262(*l*)(9)(B) is misplaced—for two independent reasons. First, section 262(*l*)(9)(B) only imposes restrictions on a biosimilar applicant's ability to "*bring* an action," not on its ability to file counterclaims in an *existing* action (as Celltrion did here). Second, Celltrion has now completed the patent exchange with Genentech pursuant to section 262(*l*)(5) that Judge White identified as a necessary step before Celltrion could bring a declaratory suit. Genentech's contrary arguments require the Court to read language into the statute that simply is not there. And they are particularly inapt in this case, which is premised on the fact that Celltrion has completed the patent dance.

### A. Section 262(*l*)(9)(B) Does Not Apply To Counterclaims In An Infringement Suit Initiated By The Reference Product Sponsor.

All parties here recognize that the "standard practice" in patent infringement cases is to allow defendants to bring declaratory judgment counterclaims. *See* p. 1, *supra*; Pls.' Br. 19. Genentech argues for a departure from that default rule here, but the text of section 262(*l*)(9)(B) does not support its argument. *See Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631

(2018) (noting that, on questions of statutory interpretation, if a statute is "unambiguous," a court's "inquiry begins with the statutory text, and ends there as well" (quotation marks omitted)). By its plain terms, section 262(*l*)(9)(B) limits only the filing of an initial complaint, not the docketing of pleadings—including answers containing counterclaims—at some later stage of an existing litigation.

That conclusion follows from the provision's operative phrase: "bring an action." To "bring" means "to cause to exist" or "institute." Merriam-Webster's Collegiate Dictionary 155 (11th ed. 2003). And an "action" is "a proceeding in a court of justice." *Id.* at 12. Together, then, to "bring an action" means "to institute legal proceedings." Black's Law Dictionary 219 (9th ed. 2009); *see also Goldenberg v. Murphy*, 108 U.S. 162, 163 (1883) ("A suit is brought when in law it is commenced."). Thus, as a matter of plain meaning, section 262(*l*)(9)(B)'s bar on "bring[ing] an action" does not prevent a defendant in an already pending lawsuit from asserting counterclaims: the act of answering, with or without including counterclaims, cannot "institute legal proceedings" that already exist.

In keeping with this straightforward understanding of the statutory language, the only court to have previously considered the question easily concluded that the term "bring an action" in section 262(*l*)(9) does not refer to the filing of counterclaims. "Asserting a counterclaim," that court observed, "is not the equivalent of commencing a lawsuit." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015), *aff'd in part and vacated in part on other grounds*, 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part and vacated in part on other grounds*, 137 S. Ct. 1664 (2017). And "[t]he BPCIA addresses only an applicant's ability to 'bring an action,' not to assert a counterclaim if placed in a position to defend against an infringement suit." *Id.*

Courts construing other statutes with similar language have reached the same conclusion. Most notably, in *Jonathan H. v. Souderton Area School District*, 562 F.3d 527 (3d Cir. 2009), the Third Circuit held that a statute of limitations under the Individuals with Disabilities Education Act ("IDEA") that requires a party to "bring a civil action" within 90 days of an adverse administrative decision does not apply to counterclaims. *Id.* at 529-30 (citing 20 U.S.C. § 1415(i)(2)). The court explained that "a defendant does not 'bring an action' by asserting a counterclaim; only a plaintiff may 'bring an action.'" *Id.* at 530; *see also Ruben A. v. El Paso Indep. Sch. Dist.*, 414 F. App'x 704 (5th Cir. 2011) (endorsing the reasoning of the Third Circuit in *Jonathan H.*). Significantly for this case, the Third Circuit held that this conclusion was "dictated" by the "plain language of the statutory text," and in particular by the ordinary meaning of the phrase "bring an action." *Id.* at 530. In other words, the Court's interpretation was not based on anything unique to the structure or purpose of the IDEA.

Similarly, in *Chandler v. District of Columbia Department of Corrections*, 145 F.3d 1355 (D.C. Cir. 1998), the D.C. Circuit addressed the scope of 28 U.S.C. § 1915(g), which places certain limits on a prisoner's ability to "bring a civil action" *in forma pauperis*. Recognizing that "the phrase 'bring a civil action' means to initiate a suit," the court had little trouble concluding that "subsection (g) plainly applies only at the time [the plaintiff] files his complaint with the district court." *Id.* at 1359. And in *Beeler-Lopez v. Dodeka, LLC*, 711 F. Supp. 2d 679, 681 (E.D. Tex. 2010), the court considered 15 U.S.C. § 1962(e), which places certain conditions on a debt collector's ability to "bring[] any legal action on a debt against any consumer." There, too, the court agreed the language referred to "institut[ing] any legal proceedings"—and so did not

apply to the conduct of a law firm that did not file the complaint in the action at issue, but rather substituted as counsel later on in the proceedings. *Id.* at 681.[2]

For its part, although Genentech purports to base its argument in part on the BPCIA's "plain language" (Pls.' Br. 15), it does not account for the actual statutory text. Genentech observes (*id.* at 16) that courts have sometimes equated counterclaims with "actions," and it points out that, in *Jonathan H.*, the Third Circuit suggested that "[t]he word 'action,' *without more*, is arguably broad enough to encompass any type of judicial proceeding, including counterclaims." 562 F.3d at 529 (emphasis added). But "action" does *not* stand alone in section 262(*l*)(9)(B). Rather, just like the statute in *Jonathan H.*, the operative phrase is "bring an action," and the Third Circuit held that this combined phrase excludes counterclaims as a matter of ordinary meaning. *Id.* at 530.

Genentech does not address the Third Circuit's reasoning on this point. Instead, it relies on the irrelevant fact that courts and commentators have (without analysis) sometimes referred to a defendant "bringing a counterclaim." Pls.' Br. 17. Notably, Genentech does not point to *any* instance in which a court adopted a different interpretation of the actual statutory language—combining "bring" and "action"—than the Third Circuit in *Jonathan H.* or the district court in *Amgen*, 2015 WL 1264756, at *9.[3] Genentech effectively tries to rewrite section 262(*l*)(9)(B) to

[2] Other authorities using similar language confirm the point. For example, the Federal Rules of Civil Procedure recognize that "a civil action is commenced by filing a complaint with the court," Fed. R. Civ. P. 3, and that a party brings a counterclaim *after* "the action was commenced," Fed. R. Civ. P. 13. Both observations are inconsistent with Genentech's position that filing a counterclaim somehow qualifies as "bring[ing] an action."

[3] Genentech argued in the earlier action that the reasoning of *Jonathan H.* should be limited to the IDEA, based on the particular "policy concerns" at issue there. D.I. 49 at 6. Significantly, however, the Third Circuit explained that its holding was "dictated by *the language* of the IDEA," and only referenced policy considerations as further support for what the statute's "plain language" already established. 562 F.3d at 530 (emphasis added). As discussed, the relevant

bar biosimilar applicants from "seeking a declaration" rather than—as the statute provides—from "bring[ing] an action under section 2201of title 28 for a declaration," 42 U.S.C. § 262(*l*)(9)(B). Genentech's argument thus reads "bring an action" completely out of the BPCIA, violating the "cardinal principle of interpretation that courts must give effect, if possible, to every clause and word of a statute." *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (quotation marks omitted).

Without statutory text to rely on, Genentech falls back on a policy argument, and insists that extending section 262(*l*)(9)(B)'s bar to apply to counterclaims would best serve the BPCIA's purposes. *See* Pls.' Br. 18. But its policy argument cannot "overcome the statute's plain language, which is [the Court's] primary guide to Congress' preferred policy." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1678 (2017). In any event, Genentech's argument fails even on its own terms, because Genentech's reading of the BPCIA subverts one of the Act's core objectives. As the Federal Circuit has explained, one of the BPCIA's key aims is to "provid[e] certainty to the [biosimilar] applicant." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (2016). Reading a limitation on counterclaims into section 262(*l*)(9)(B) conflicts with that goal. Genentech's desired reading would permit it to strategically withdraw infringement claims from this litigation—as it has done in other actions involving the parties here—while continuing to hold those allegations in reserve. Yet, according to Genentech, Celltrion would be barred from bringing any counterclaims to ensure the timely litigation of those disputed infringement allegations. That proposed interpretation hardly makes sense of a statutory provision that was designed to ensure certainty to clear the way for the commercial launch of biosimilar products. *See Amgen*, 827 F.3d at 1063.

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text of the IDEA—"bring a civil action"—is materially indistinguishable from the text of section 262(*l*)(9)(B).

Genentech acknowledges that Celltrion's desire for certainty with respect to all of the asserted patents "may have merit" (Pls.' Br. 19), but argues that the harsh result of dismissal is needed to make sure that paragraph (9)(B) is effective. Contrary to Genentech's assertion, a statutory bar that prevents biosimilar applicants from initiating new civil actions for declaratory relief in its preferred forum is a meaningful sanction that fully protects the patent dance. There is thus no policy imperative to distort paragraph (9)(B)'s text by applying it to counterclaims.

### B. Celltrion Did Not Fail To Complete Any Actions Enumerated In Section 262(*l*)(9)(B).

Even if section 262(*l*)(9)(B) had any potential application to counterclaims, it would not bar Celltrion's declaratory claims here. As even Genentech notes (Pls.' Br. 15), "Section 262(*l*)(9)(B) is triggered by five specific failures to act." *See* 42 U.S.C. § 262(*l*)(9)(B) (listing "fail[ure] to complete an action required of the [biosimilar] applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A)"). In arguing for dismissal under this provision, Genentech makes three claims: (1) that Celltrion failed to complete its obligations under paragraph (5) within a putative statutory deadline; (2) that Celltrion failed to allege its compliance with paragraph (6)(C)(i); and (3) that Celltrion "repudiated" the patent dance and thereby "forfeited" its rights under the BPCIA. Each contention lacks merit and fails to account for the actions Celltrion has taken to remove any doubt about its statutory compliance following Judge White's decision.

#### *1. Celltrion has completed its paragraph (5) obligations.*

Genentech relies first on Judge White's holding that Celltrion failed to complete its obligations under section 262(*l*)(5) by the time it filed suit in California. *See Celltrion*, 2018 WL 2448254, at *5. As mentioned, Celltrion respectfully disagrees with Judge White's conclusion and has accordingly filed an appeal: Celltrion carried out its obligations under paragraph (5) by

providing notice to Genentech that it wished to litigate all of the patents on Genentech's paragraph (3)(A) List. *See* p. 5, *supra*. But even assuming *arguendo* that Judge White's interpretation of the BPCIA is correct, Celltrion has since taken additional measures to eliminate any doubt about its compliance with the statute. In particular, Celltrion has now completed its paragraph (5) exchanges with Genentech. *See* pp. 5-6, *supra*. That fact forecloses Genentech's attempt to rely on section 262(*l*)(9)(B) and Judge White's opinion.

In response, Genentech contends that Celltrion's designation and exchange of patent lists under paragraph (5) was untimely. According to Genentech, the statute "contemplate[s]" that a biosimilar applicant will submit its (5)(A) number to the reference product sponsor within 15 days of the "start[] [of] negotiations under 42 U.S.C. § 262(*l*)(4)"—something that Genentech asserts Celltrion did not do. Pls.' Br. 13. But Genentech's missed-deadline argument is divorced from the text of the statute: there simply is no provision anywhere in paragraph (5) that imposes a time limit on the applicant's transmission of its (5)(A) number.

To be sure, as Genentech points out, *paragraph (4)* gives the parties 15 days to negotiate and agree on a list of patents that will be the subject of a first round of litigation. But that paragraph goes on to state that in the event of a failure to agree, "the provisions of *paragraph (5)* shall apply to the parties" (emphasis added). Paragraph (5), in turn, requires the applicant to "notify the reference product sponsor of the number of patents that" the applicant wishes to litigate, but contains no deadline on any such notice. 42 U.S.C. § 262(*l*)(5)(A). Certainly nothing in paragraph (5) suggests the biosimilar applicant must provide its (5)(A) designation on the very first day after the time to negotiate has expired.

Indeed, the inclusion of an express deadline in paragraph (4)—as well as in several other paragraphs of section 262(*l*)—only underscores that Congress knew how to impose strict time

limits when it wished to, but chose not to with respect to the paragraph (5)(A) designation. *See, e.g., Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest."). The Supreme Court made precisely this point when interpreting the BPCIA, as the Court rejected a reference product sponsor's attempt to read a timing requirement into the statute that Congress did not specify. *See Sandoz*, 137 S. Ct. at 1677 ("Had Congress intended to impose two timing requirements in § 262(*l*)(8)(A), it presumably would have done so expressly as it did in the immediately following subparagraph." (quotation marks omitted)). In the end, even Genentech tacitly acknowledges that paragraph (5)(A) does not contain any timing requirement: its brief must cite paragraph (4) for the deadline it now asks the Court to read into paragraph (5)(A). Pls.' Br. 13 (citing 42 U.S.C. § 262(*l*)(4)(b)).[4]

***2. The statute does not require Celltrion to plead compliance with its paragraph (6)(C)(i) obligations.***

Genentech next argues (Pls.' Br. 15) that Celltrion's counterclaims should be dismissed for failure to plead compliance with paragraph (6)(C)(i). That provision directs the biosimilar applicant to provide notice to the Secretary of Health and Human Services within 30 days of the

[4] Nothing in Judge White's opinion is to the contrary. Genentech quotes Judge White's observation that, after the parties failed to reach an agreement under paragraph (4), the "BPCIA required both Celltrion and Genentech to complete the steps outlined in Section (*l*)(5)." Pls.' Br. 13 (quoting *Celltrion*, 2018 WL 2448254, at *5). But Judge White's opinion did not endorse Genentech's assumed 15-day deadline. Indeed, Judge White cautioned against "improperly conflat[ing] Sections (*l*)(4) and (*l*)(5)." *Celltrion*, 2018 WL 2448254, at *6. Nor is Genentech correct that the courts must read a 15-day deadline into paragraph (5) to "give[] meaning" to the legislatively enacted 15-day deadline in paragraph (4). Pls.' Br. 14. The deadline in paragraph (4) limits the negotiations that must take place under that paragraph—with or without a separate time limit in paragraph (5).

service of the reference product sponsor's paragraph (6)(A) complaint. 42 U.S.C. § 262(*l*)(6)(C)(i). In fact, however, Celltrion *did* provide the requisite notice to the Secretary within the 30-day statutory deadline by sending it by certified mail to the Secretary on August 21, 2018—fewer than 30 days after the complaint was served on July 27, 2018. *See generally* Declaration of Kevin J. DeJong (attached hereto). This fact completely undercuts Genentech's argument. Genentech appears to object that Celltrion did not include allegations about this notice in its counterclaims. But there is an obvious reason for that: the 21-day deadline for Celltrion to answer Genentech's complaint under Rule 12 came *before* the 30-day deadline to provide notice under paragraph (6)(C)(i). As a general matter, Celltrion had no obligation to include allegations merely to "anticipate or overcome [Genentech's] affirmative defenses" under paragraph (9)(B). *Schmidt v. Skolas*, 770 F.3d 241, 248 (3d Cir. 2014). Certainly, Celltrion cannot be faulted for omitting factual allegations based on a notice that Celltrion quite properly provided to the Secretary *after* filing its answer with its counterclaims.[5]

***3. Genentech's "repudiation" theory is meritless.***

Beyond its paragraph (5) and (6) arguments, Genentech fails to identify any other enumerated action that Celltrion has "fail[ed] to complete"—as it must to establish that section 262(*l*)(9)(B) precludes Celltrion's counterclaims. Instead, Genentech argues that Celltrion's counterclaims are barred by that provision because Celltrion "abandoned the patent dance" when it brought its declaratory suit in California. Pls.' Br. 13. But Genentech's premise is mistaken: Celltrion displayed no intention of "abandon[ing] the patent dance" through its California action. Rather, Celltrion's suit simply reflected the fact that, once it provided notice that it wished to litigate all of the patents on Genentech's (3)(A) List, nothing remained for the parties to

[5] If, however, the Court agrees with Genentech that a defendant must plead compliance with the notification requirement in paragraph (6)(C)(i), Celltrion respectfully requests an opportunity to amend its answer to include the relevant facts that are set forth in the DeJong Declaration.

negotiate. *See* p. 5, *supra*. At the time it filed suit, in other words, Celltrion reasonably believed that it had completed all of the steps of the patent dance. And when Judge White disagreed with that view, Celltrion promptly completed the steps that Judge White had identified as outstanding. In short, Celltrion's actions displayed a commitment to finishing the dance—not renouncing it.

In any event, even if Genentech's allegations of abandonment *did* have any basis in fact (they do not), section 262(*l*)(9)(B) is triggered by five specific (and specifically enumerated) failures to act—not by some ill-defined intent to "abandon[] the patent dance." Once again, Genentech's arguments fail to address the actual language of the statute.

#### *4. The present action is premised on Celltrion's compliance with the requirements of the patent dance.*

Finally, Genentech's arguments for dismissal under paragraph (9)(B) are particularly inapt in this case, which is premised on the fact that Celltrion *has* completed all required steps of the patent dance. According to Genentech's complaint, this suit arises under 42 U.S.C. § 262(*l*)(6). Compl., D.I. 1, ¶ 17. That is the only fact that distinguishes this suit from the one Genentech previously filed in this District: as Genentech explains (Pls.' Br. 2), its allegations are otherwise identical to those in the related case. Thus, contrary to Genentech's protestation (*id.* at 8), this suit plainly *is* "predicated on the understanding that Celltrion completed the patent dance" because the only way that *this* suit will move forward is if the Court agrees that Celltrion has complied with its obligations under 42 U.S.C. § 262(*l*). Accordingly, it is illogical to dismiss Celltrion's counterclaims on the grounds that Celltrion has not complied with those obligations: if the Court concludes that Celltrion did not complete the patent dance, then the result would be to dismiss this backup action by Genentech entirely.

## CONCLUSION

Section 262(*l*)(9)(B) does not bar Celltrion's counterclaims in this action. Accordingly,

the Court should deny Genentech's motion to dismiss.

Respectfully submitted,

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